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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,869

10/12/2005

Anders Lehmann

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7470 7590 09/15/2008

WHITE & CASE LLP  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER

LEWIS, AMY A

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

09/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,869	<b>Applicant(s)</b> LEHMANN ET AL.	
	<b>Examiner</b> Amy A. Lewis	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-28 is/are pending in the application.
- 4a) Of the above claim(s) 19-23, 26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-18, 24, 25 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/19/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/18/2008 has been entered.

Applicants' arguments, also filed 6/18/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Response to Applicant's Arguments regarding Election of Species Requirement:***

Applicants again traverse the election requirement and request examination of the entire species mGluR5 antagonists. This request was addressed in the previous office action and was made FINAL. This requirement is maintained and the finality is again reiterated for the reasons of record. Further, in view of the sensitivity or specificity of said receptors, and the various functionalities encompassed among those compounds that are deemed to be metabotropic glutamate receptor 5 (mGluR5) antagonists, an undue search burden is presented to the Examiner.

***Claim Rejections - 35 USC § 112: Enablement***

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Claims 17, 18, 24, 25 and 28 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. This rejection is maintained over claims 17, 18, 24, 25, and 28, and newly applied to claims 15 and 16 as well.

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As stated in the previous office action, the claims are directed to the prevention of reflux and the prevention of regurgitation. Applicants argue that amendments to the claims to remove the word “prevention” overcomes this rejection. However, in looking to the specification (at page 2), the object of the instant invention encompasses inhibition and treatment of TLESRs and “thereby preventing” (see line 13 specifically). Thus, due to the definition of treatment and inhibition also encompassing prevention the rejection is maintained for the reasons of record.

***Claim Rejections - 35 USC § 112:***

In the last Office Action claims 15-18, 24, 25 and 28 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This rejection is also maintained for the reasons of record and further below.

Applicants argue that the claims are amended to recite that the active compound is administered to a patient suffering from GERD, thus obviating the rejection. This is not persuasive due to the construction of the claims as amended. While the claims recite “[a] method for the inhibition of ...(TLESRs)” there is no specific connection of this preamble with the active step of the claims, which is administering the compound to a patient suffering from

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GERD. Thus the claims still potentially include treatment of patients who have TLESRs related to various unrelated etiologic factors (as discussed in the previous office action). Therefore the claims remain rejected because the claims still contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. See also the rejection under 35 U.S.C. § 112, second paragraph, below.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-18, 24, 25, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While the claims recite “[a] method for the inhibition of ...(TLESRs)” there is no specific connection of this preamble with the active step of the claims, which is administering the compound to a patient suffering from GERD. Therefore, it is unclear if the patients being treated have TLESR concomitant with GERD or if the patients can also include those whom have TLESR and not GERD. In other words, there is no connection of the administration of the active compound to the GERD patient to the method of treating TLESR: it is unclear if the method is treating the patient which has TLESR or GERD.

### ***Conclusion***

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is 571-272-9032. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy A Lewis/  
Examiner, Art Unit 1614

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614